DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION
WASHINGTON DC 20420

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HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE PROGRAM ANNOUNCEMENT INVITING RESEARCH ON

PREVENTION OF ERRORS AND INJURIES IN CLINICAL CARE

1. Purpose. This Program Announcement announces the availability of designated research funds to support health services research focused on the *promotion of patient safety and prevention of adverse events.* This is an initiative of the Health Services Research and Development Service (HSR&D), Office of Research and Development, Department of Veterans Affairs (VA).

2. Eligibility. Investigators who hold a VA appointment of at least 5/8 time are eligible to apply. Any questions about eligibility may be referred to the HSR&D Eligibility Coordinator (see below).

3. Background.

Patient safety is health care's prime directive -- "First, do no harm." This ancient dictum attained a new place in the public consciousness with the November 1999 publication of an Institute of Medicine (IoM) report claiming that between 44,000 and 98,000 annual in-hospital deaths are due to "medical errors" (IoM, 1999). Extensive media attention, Congressional hearings and Presidential mandates swiftly followed. Throughout the country, hospitals, insurers, and research organizations took up the cause. For the Veterans Health Administration (VHA), where important initiatives were already underway, the IoM report was a forceful reminder of the need to keep patient safety as a constant focus in efforts to improve health care quality.

A series of significant activities has earned national recognition for VHA as a leader in patient safety. In 1997, VA was a founding member of the National Patient Safety Partnership (along with the American Association of Medical Colleges, American Hospital Association, American Medical Association, American Nurses Association, and the Institute for Healthcare Improvement). Soon to follow were the Patient Safety Improvement Policy with its Patient Safety Registry and Patient Safety Improvement Oversight Committee; as well as the National Center for Patient Safety, VA's Patient Safety Improvement Awards Program, and collaboration with the National Patient Safety Foundation, a not-for-profit foundation associated with the American Medical Association. VA innovations, such as bar-coding of prescription medications and patient identification bracelets, have been widely sited. In May 1998, HSR&D published its first solicitation for research projects focused on patient safety (IL 12-98-003), and has funded, to date, three projects responding to that announcement. In November 1998, VHA published an announcement for Patient Safety Centers of Inquiry (VHA Directive 98-050) and established, early in 1999, four.

Of the thousands of deaths and injuries due to medical error [the actual number is the subject of dispute (Leape, 2000; McDonald et al., 2000; Sox & Woloshin, 2000)], the Institute of Medicine report blames the vast majority not on the intentional or negligent actions of individual health care workers, but on *faults in the system*. Research on accidents in health care and other types of complex systems bears this out (e.g., Laffel & Blumenthal, 1989; Laffel & Berwick, 1992). In

addition to, and contributing to, human errors are problems in the physical environment, as well as problems in the organization, coordination, communication, scheduling, supervision, or management of complex tasks. Often, errors or avoidable bad outcomes are the result of the combination or alignment of multiple individual factors or failures (Woods, et al., 1994), or the gaps inherent in complex technical work (Cook, Render, & Woods, 2000). Certainly, the causes of preventable bad outcomes in health care are varied and numerous. And certainly, whatever the actual number of deaths and serious injuries, the problem demands continuing attention.

HSR&D support for research related to patient safety includes projects that responded to our first call for such research as well as some that preceded that call. Among the pertinent projects initiated in the past 5 years, one examined the usefulness of aberrant laboratory results as indicators of preventable hospital complications (Hofer, HSR&D Project No. IIR 94-131). Others are developing systems and testing interventions to reduce medication errors, through greater involvement of hospital pharmacists, and real-time computerized surveillance of all adverse drug events, and patient profiling (Rosenthal, SAF 98-152; Hurdle, SAF 98-122; Glassman, SAF 98-144). HSR&D researchers have also focused on the prevention of falls among frail, elderly veterans, in nursing homes or in their own homes (e.g., deVito, IIR 94-003). VA's extensive computerized databases, comprehensive range of health care settings, management practices and financing mechanisms facilitate types of patient safety research that may not be possible in other arenas.

4. Scope of HSR&D Research Interests.

With this solicitation, HSR&D will support additional research to reduce the most common types of medical error (e.g., adverse drug events, hospital-acquired infections, and falls) but **especially encourages exploration of relatively new areas and new approaches.**

Prevention. Studies should focus on the prevention of adverse events. Identifying accidents, "close-calls," "incidents", and "sentinel events" can point toward strategies for understanding their causes and implementation of methods to reduce or eliminate them.

Health Care Settings. Studies may address issues of patient safety in any pertinent setting -- VA facilities or VA-contracted care, including inpatient medical units, intensive care, surgery, emergency, laboratories, pharmacies, food services, and long-term care settings. **Note:** Of particular interest is safety in *outpatient settings*, including clinics, mental health and substance abuse treatment centers, outpatient surgery centers, and patients' homes.

Target Audience. Studies may focus on the performance of health care providers in general or particular groups of providers (e.g., physicians, nurses, pharmacists), the role of managers, informal caregivers, and patients' involvement in their own care.

New Tools or Strategies. Investigators are encouraged to study new or adapted tools or strategies for the systematic prevention of errors and injuries and/or for promoting a culture of patient safety.

Gaps in Processes and Systems. Studies may address how changes in organization, management, communication, scheduling, etc. as well as new knowledge or technology affect patient safety.

Physical Factors. Studies may address issues related to environmental design, equipment (including human-machine interfaces), devices to improve patient mobility or communication, and other physical features that could affect patient safety.

Technology. High tech tools such as computerized decision support systems *and* low tech approaches, such as accurate pill-splitters, are appropriate.

Role of Violence. Some patient injuries or adverse outcomes result from physical violence against patients by other patients or unintended self-inflicted injuries due to patients' violent or irrational behavior (or efforts to constrain it). Studies to describe the incidence of such events and evaluate methods to reduce them are appropriate for this solicitation. **Note:** Studies of *criminal activity* that threatens patient safety are *not appropriate* for this solicitation.

Relationship between Working Conditions and Patient Safety. Components of complex systems, such as health care delivery, interact in ways that may not be readily apparent. HSR&D is interested in research on organizational, systemic, structural, or exposure factors in health care settings that may affect the safety and health of *both* patients and workers. For example, vaccinating staff against flu or other contagious diseases may have a protective effect for patients (and other workers).

5. Sample Research Issues: Investigators are advised to develop projects that will build on, without undue duplication, the work of other funded HSR&D investigators and relevant research funded outside VA, especially by the Agency for Healthcare Research and Quality.

The following are illustrative examples of research foci appropriate for this solicitation:

- The applicability to VA of patient safety initiatives developed in the private sector, or vice-versa. This may include initiatives developed in the health care or in other arenas (e.g., transportation, manufacturing, human factors engineering, cognitive psychology).

- Indicators of potential errors, including provider-initiated actions such as sudden medication stop orders, antidote ordering, abnormal lab values, and patient-initiated actions including elopement and suicide.

- Methods for empowering patients and family members to help protect against medical errors and to recognize risks and warning signs.

- Cost effectiveness of alternative approaches (e.g., incentives or sanctions) to reduce or prevent medical errors.

- Direct and indirect costs of medical errors in VA and their impact on patients' loyalty to VA.

- Methods for mitigating the negative effects of factors such as stress, fatigue, and interruptions on the performance of health care providers.

- Problematic oral communications (unsaid, misheard, or ambiguous) among providers and between provider and patient.

- Methods for discerning, documenting and communicating information about patient co-morbidities, current medications, drug and food allergies, and advance directives.

6. Letter of Intent. This solicitation follows established procedures for HSR&D's Investigator-Initiated Research program. All applicants must first submit a Letter of Intent (LOI), in the format specified in HSR&D's "Instructions for Submitting a Letter of Intent, January 2000," [available at all VA Research and Development (R&D) offices and on the VA research home page at http://www.va.gov/resdev. LOIs will be reviewed for relevance to this announcement and scientific merit. No individual may be named as Principal Investigator (PI) or co-PI on more than one LOI submitted in response to this announcement. LOIs responding to this announcement will be reviewed monthly, along with other LOIs submitted to HSR&D. Letters received by the last business day of a month will be reviewed the following month.

7. Proposal Preparation and Submission. Applicants with an approved LOI will be invited to submit a full research proposal. Proposals are to be prepared in accordance with HSR&D's "Instructions for Preparing Investigator-Initiated Research Proposals, Oct. 1997" (available at all R&D offices and on the web at http://www.va.gov/resdev. The initial proposal receipt date is May I, 2001. Proposals will continue to be accepted each November 1, and May 1, until further notice.

8. Research Methods. All proposed studies are expected to use research designs and methods that maximize the validity, reliability, generalizability and usefulness of findings. While the research needs to be grounded in the realities of VA practice and address real world information needs, it also needs to have a clear theoretical framework, demonstrate familiarity with the pertinent literature, and employ a data collection and analysis strategy that will yield valid conclusions. The multidisciplinary nature of health services research should be evident in the formulation of the research questions, and the methodological approach may draw from any, or several, discipline(s). Study teams should generally include individuals with experience and expertise in clinical and non-clinical fields, including pertinent social scientists and research methodologists. The research needs to be designed to maximize the eventual application of findings and conclusions.

9. Review. Proposals received in response to this announcement will undergo peer review, along with other IIR projects, by the HSR&D Scientific Review and Evaluation Board (SREB). The review is rigorous and standards very high; both scientific merit and expected contribution to improving VA health services are considered. Investigators are expected to develop and describe their research plan completely and in detail. Proposals recommended for approval will be considered for funding.

10. Funding. HSR&D has dedicated a total of up to $3 million for this initiative over the next four years and plans to initiate the first new projects in the fourth quarter of FY 2001. Proposals may request up to 5 years of funding; however, projects that can produce useful findings in a shorter timeframe are encouraged. There is no preset limit on project cost; however, the research design is expected to be appropriate and efficient, with all budget categories well justified. In planning project budgets, applicants are reminded to adhere to R&D guidelines regarding allowable use of research funds for specific items and restrictions on the use of research funds for equipment and development of computer software.

11. Inquiries. For further information regarding this solicitation, contact Claire Maklan, MPH, PhD, Chief of Scientific Development, HSR&D, at claire.maklan@hq.med.va.gov or (202) 273-8287. For information about review procedures, contact Martha Bryan, EdD, Scientific Review Program Manager, at (202) 408-3665 or martha.bryan@hq.med.va.gov.

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